

Serial No. 10/369,819, filed February 27, 2006  
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REMARKS

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**I. Claim Amendments**

Claim 14 has been amended to recite a method for inhibiting gastric acid secretion comprising the administration of a therapeutically effective amount of the claimed compound. Support is found on page 10, lines 7-8, of the specification. It is submitted that no new matter has been introduced by the claim amendment.

**II. The Examiner's Response**

Applicants respectfully disagree with the Examiner that their previous response to the restriction/election requirement was not fully responsive. In response to the requirement to elect a single disclosed method, i.e., a specific disease, Applicants elected the inhibition of gastric acid secretion as disclosed on page 10, lines 7-8, of the specification. Contrary to the Examiner's allegation, the statement appearing on page 10, lines 7-8, is entirely in the singular form and not in the plural form: "These active substances are useful for inhibiting gastric acid secretion in mammals and man."

The Examiner has quoted and mistakenly relied upon the subsequent and broader disclosure where it is stated that the claimed substances, "[i]n a more general sense...may be used for prevention and treatment of gastric acid related diseases.." However, Applicants did not elect the general pluralized form, i.e., gastric acid related diseases. Rather, Applicants elected the single disclosed method, i.e., inhibiting gastric acid secretion.

The Office has recognized the inhibition of gastric acid secretion as a single and searchable method.. In this regard, the Examiner's attention is directed to the following sampling of granted patents having claims directed to the single method, i.e., the inhibition of gastric acid secretion:

US 6,613,775/Claim 10. A *method* for inhibiting *gastric acid secretion* comprising administering to a mammal in need of such *inhibition* an effective amount of a compound according to any one of claims 1 to 4.

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US 6,610,323/Claim 25. A *method* for improving *inhibition of gastric acid secretion* which comprises administering to a patient in need thereof, an oral pharmaceutical dosage form as defined in any one of claims 1-7, 8 or 9.

US 6,605,303/Claim 27. A *method* for improving *inhibition of gastric acid secretion* comprising administering to a patient in need thereof the dosage form as claimed in any one of claims 1-4, 5-9, 14-16, 11, 17-22 or 10, 12, 13.

US 6,579,884/Claim 7. A *method* for inhibiting *gastric acid secretion* which comprises administering to a mammal in need of such *inhibition* an effective amount of a compound according to any one of claims 1 or 2.

US 6,518,270/Claim 14. A *method* for inhibiting *gastric acid secretion* comprising administering to a patient in need of such *inhibition* an effective amount of a compound according to any one of claims 1 to 10.

US 6,511,996/Claim 7. A *method* for inhibiting *gastric acid secretion* which comprises administration of a therapeutically effective amount of the potassium salt of (S)-omeprazole form B as claimed in claim 1 or 2 to a patient in need of such *inhibition*.

US 6,380,234/Claim 2. A *method* of providing a *gastric acid secretion* inhibitory effect to a subject in need thereof, comprising:  
orally administering to the subject a stabilized pharmaceutical composition, comprising:  
an effective amount of a 2-[(2-pyridyl)methylsulfinyl]benzimidazole compound or a pharmaceutically acceptable salt thereof having a *gastric acid secretion* inhibitory property;  
a basic inorganic salt stabilizing agent, comprising sodium carbonate, in an amount effective to stabilize the composition, the benzimidazole compound or its salt being in contact with the stabilizing agent evenly; and  
an enteric coating for the composition.

US 6,313,137/Claim 12. A *method* for inhibiting *gastric acid secretion* which comprises administering to a mammal in need of such *inhibition* an effective amount of a compound or salt thereof according to any one of claims 1 to 5.

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US 6,265,415/Claim 26. A *method* for inhibiting *gastric acid secretion* which comprises administering to a mammal, in need of such *inhibition* an effective amount of a compound according to any one of claims 1 to 18.

Applicants and the public have relied upon this precedence and the Examiner should not now be permitted to unilaterally disrupt that trust between the public and the Office.

For all of the foregoing reasons, Applicants respectfully submit that the Examiner is incorrect. Applicants' previous response was fully responsive. The elected disease "inhibition of gastric acid secretion" is a single disclosed method and not in the plural form as alleged by the Examiner.

Nevertheless, to be fully responsive to the outstanding Office Action, which Applicants repeat was issued in error, Applicants elect "reflux esophagitis" as disclosed on page 10, line 9, of the specification.

### **III. Traversal of the Restriction Requirement**

It is alleged that the application contains the following groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:

Group I: claims 1-12 directed to a compound/composition and process for making;

Group II: claim 14 directed to multiple uses; and

Group III: claim 15 directed to the claimed composition further comprising an additional

Applicants do not traverse the restriction with respect to Group III. However, in view of 37 C.F.R. §1.475(b)(3), Applicants traverse the restriction with respect to Groups I and II.

As correctly noted by the Examiner, 37 C.F.R. §1.475(b)(3) provides that a national stage application will be considered to have unity of invention if the claims are directed to a product, a process for manufacture of the product and a use of the product.

Amended claim 14 (Group II) is directed to a single disclosed method: inhibition of gastric acid secretion. Therefore, in view of 37 C.F.R. §1.475(b)(3), the restriction between Groups I and II is moot.

Moreover, method of treatment claim 14 is dependent on the administration of the compound of claims 1-6. Thus, Groups I and II share the same special technical feature, i.e., the compounds of claims 1-6 (Group I) and the administration of the compounds of claims 1-6

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(Group II). Therefore, the examination of method of treatment claim 14 in the same application as compound claims 1-6 appears to be required by PCT Rules 13.1 and 13.2.

Furthermore, the rejoinder of claim 14 would be economically prudent for both the Office and Applicants. Claim 14 should be rejoined and examined in this application with the related compound claims which are administered in accordance with the method of claim 14.

### CONCLUSION

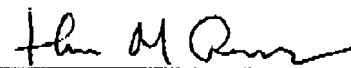
Applicants' previous response was fully responsive. The elected disease "inhibition of gastric acid secretion" is a single disclosed method and not in the plural form as alleged by the Examiner. Moreover, the indication is properly searchable by the Examiner without undue burden.

Applicants submit that the restriction of Groups I and II violates 37 C.F.R. §1.475(b)(3) and PCT Rules 13.1 and 13.2. Withdrawal of the restriction requirement with regard to Group II and rejoinder and examination of claim 14 in the subject application is requested.

Any fees due in connection with this response should be charged to Deposit Account No. 23-1703.

Dated: July 16, 2007

Respectfully submitted,

  
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